



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ :

A61F

A2

(11) International Publication Number:

WO 00/67661

(43) International Publication Date: 16 November 2000 (16.11.00)

(21) International Application Number: PCT/US00/13129

(22) International Filing Date: 12 May 2000 (12.05.00)

(30) Priority Data:

09/310,891	12 May 1999 (12.05.99)	US
09/312,785	17 May 1999 (17.05.99)	US
09/330,498	11 June 1999 (11.06.99)	US

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(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

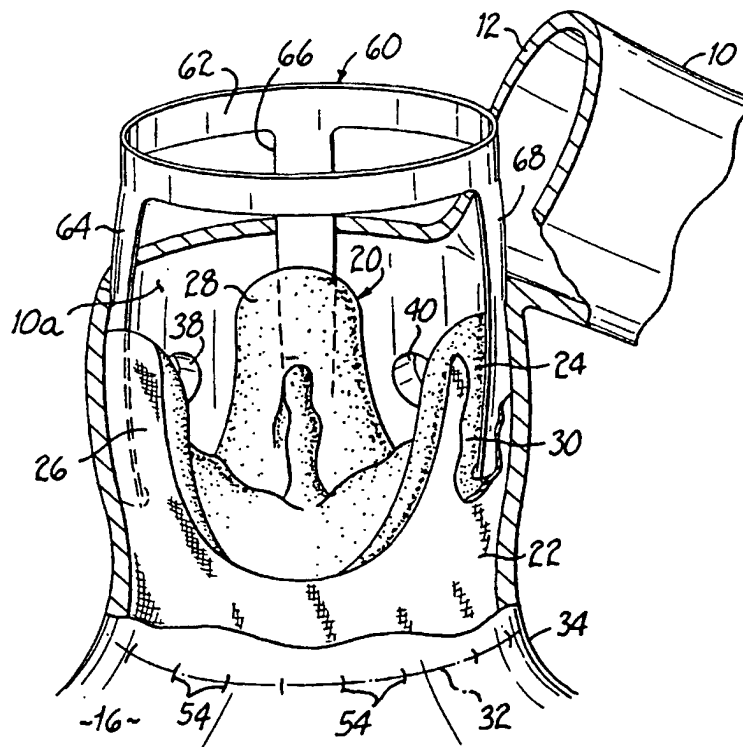
Published

Without international search report and to be republished upon receipt of that report.

(54) Title: HEART VALVE AND APPARATUS FOR REPLACEMENT THEREOF, BLOOD VESSEL LEAK DETECTOR AND TEMPORARY PACEMAKER LEAD

(57) Abstract

Apparatus and methods for replacing a heart valve within a vessel (10). The apparatus includes a replacement heart valve (20) and a plurality of commissure stabilizers (64, 66, 68) temporarily connected to the commissures of the heart valve (20) in a removable manner. A cannulating device (320) which, in a first embodiment, includes a cannula (324), a hub portion, and a retaining member (332) extending from the hub portion. In a second embodiment, a clamp (348) is coupled with the hub portion (350) and may be moved between open and closed positions to retain the vessel (342) in a sealed condition on the cannula. A temporary pacemaker lead including a wire (434) having an electrically conductive portion, a first connector portion (438) on the wire, and an electrode (430) having a second connector portion (436).



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HEART VALVE AND APPARATUS FOR REPLACEMENT THEREOF, BLOOD VESSEL LEAK DETECTOR AND TEMPORARY PACEMAKER LEAD

Background of the Invention

A popular option for aortic valve replacement is to retain the native aortic root and the normal coronary artery attachments and secure the replacement prosthesis inside the patient's own aorta. With this procedure, only the valve is replaced and not the entire root. It is unnecessary to re-attach the coronary arteries and, should repeat surgery be necessary, a surgeon must only replace the valve and not an entire section of the aorta. When a surgeon replaces the aortic valve in this manner, the patient is first placed on a heart-lung machine and the section of the aorta having the aortic valve is clamped off to allow access. That section of the aorta is therefore collapsed and unpressurized leaving a pressurized section connected to the heart-lung machine. The unpressurized section of aorta is then opened and the diseased valve is removed in its entirety, including careful removal of calcium deposits within the aorta and annulus. The aorta and sinotubular junction are then sized and the surgeon prepares the appropriate replacement valve. The surgeon then sutures the inflow or annular end of the replacement valve into the inside of the aorta. When these sutures are drawn tight, the valve is pulled inside the aorta when approximately 20 sutures are then applied around the annular end. The

commisures of the replacement valve, which extend from the annular end, may or may not need to be affixed to the aorta as discussed below.

Two major types of prosthetic or replacement heart valves exist. The first general type of valve is a mechanical prosthesis which includes commisures that are self-supporting and do not need to be affixed to the aortic wall. Mechanical prostheses are generally formed entirely of artificial material, such as carbon fiber, titanium, dacron and teflon. While these mechanical prostheses are durable, relatively quick to implant and generally easy to manipulate during surgery, they also have certain disadvantages. For example, due to the artificial materials used in their construction, blood clots can form on the valve and subsequently cause valve failure. If the clot dislodges from the valve, the clot can lodge in a downstream vessel and cause stroke or organ ischemia. For these reasons, patients with mechanical heart valves must take anticoagulants for the rest of their lives. Anticoagulants bring about their own complications in some patients, including internal bleeding or other side effects.

The second major type of prosthetic or replacement heart valve is a biologic valve. This category includes valves harvested from human cadavers, i.e., allografts or homografts, or animal tissue generally harvested from cows and pigs. More recently, there has been increasing effort to develop synthetic biologically compatible materials to substitute for these natural tissues. Among their advantages, biologic prostheses generally do not require lifelong anticoagulation as they do not often lead to clot formation. These valves are provided in stented or unstented forms. A

stented valve includes a permanent, rigid frame for supporting the valve, including the commissures, during and after implantation. The frames can take the form of a wire or other metal framework or a plastic frame encased within a flexible fabric covering. Unstented valves do not have built-in commissure support so surgeons must use their skill and best judgement to determine the optimal site of implantation inside the patient's native aorta to maintain valve competence. When securing the valve commissures, obstruction of the patient's native coronary arteries must be avoided or myocardial infarction may result.

There are many limitations to procedures utilizing permanently stented biologic replacement valves. First, allografts (human cadaver donor valves) are not generally available with permanent frames or stents. Second, the frames or stents can take up valuable space inside the aorta such that there is a narrowing at the site of valve implantation. This narrowing leads to pressure gradients and increased loads on the left ventricle and, therefore, increased incidence of hypertrophy and reduced patient survival. The frame includes artificial materials which can increase the risk of new infection or perpetuate an existing infection. It is also very important to realize that although the permanent frames or stents guarantee alignment of the commissures, they cause very high stresses on the commissures when the valve cusps move between open and closed positions. A patient's natural commissures are not placed under significant strain during opening and closing of the valve due to the natural resilience of the aorta. On the other hand, artificially mounted valves place the

commisures under strain during operation of the valve due to the rigid materials of the frame. Over time, the valve cusps tend to decay under this strain and manifest calcification and tears which can lead to valve failure.

In many situations, biologic replacement heart valves are preferred in the unstented form due to the drawbacks mentioned above. Such valves are more resistant to infection when implanted free of any foreign material attachments, such as stents or frames. Also, the heart valve is more efficient when used without a stent. Efficiency refers to the pressure gradient across the valve during use. Natural human valves have almost no pressure gradient. When a natural heart valve is replaced by a biologic heart valve with a low pressure gradient, complications such as hypertrophy arise less often and result in improved patient survival.

Despite the known advantages of using biologic prosthetic heart valves without artificial supporting devices such as permanent stents or frames, relatively few surgeons employ this surgical technique due to its high level of difficulty. When unsupported or unstented by artificial devices, such as permanent stents, biologic replacement heart valves have a flimsy, soft and flexible nature. That is, the commisures of the heart valve do not support themselves in the proper orientation for implantation. For these reasons, it is very difficult to secure the commisures properly into place. In this regard, the surgeon must generally suture the individual commisures of the heart valve in exactly the proper orientation to allow the valve to fully and properly function.

During valve replacement surgery, an L-shaped retractor is placed inside the aorta to pull it open for access purposes. While this provides exposure, it distorts the aorta and may give the surgeon an incorrect impression of the correct valve position. Next, and especially with regard to unstented biologic valve procedures, the surgeon must guarantee that the commissures pass straight up the aorta at roughly right angles to the plane of the annulus. There is very little technology to help the surgeon correctly place the stentless replacement valve. To help confirm that the leaflets are correctly spaced at 120° apart, surgeons may use a disc having markings 120° apart. The surgeon can use this to roughly estimate the spacing by placing it near the distal ends of the commissures. However, this provides only a rough guide. For example, it is possible to equally space the commissures at the upper end and still have a valve placed in a skewed position. Finally, the aorta is not a straight tube at the surgical site, but instead flares outward at the surgical site. The valve must conform to the flare of the aorta at this location. Once the surgeon has completed an inspection for these three elements, i.e., correct spacing at approximately 120° between the commissures, correct perpendicular position of the commissures relative to the annulus plane, and appropriate conformation to the flare of the aorta, the surgeon must suture the commissures to the wall of the aorta. As this is done, it is necessary to make sure there is no encroachment on the ostia or origins of the coronary arteries. After the valve commissures are attached to the aorta and proper orientation and positioning is confirmed, the surgeon closes the aorta.

Following surgery, there is a risk that the aorta will dilate at the sinotubular junction months or years later and draw the valve commissures and attached cusps apart from each other. This will cause insufficiency and failure due to leakage through the valve. There is a further
5 need for methods to ensure that late enlargement of the sinotubular junction does not necessitate reoperation for late valve insufficiency and failure.

In general, there is an increasing need for devices which improve the efficiency and reliability of implanting replacement heart valves. In conjunction with this, there is a need to improve these procedures so
10 that all surgeons, not just those with the highest skill levels, can implant heart valves with superior results.

Blood vessels must frequently be cannulated with fine tubes, i.e., cannulas, to allow injection of fluids into the vessels. When the vessels are large enough, such as several millimeters in diameter, relatively
15 large and rigid cannulas may be placed inside the vessel. A tie is then typically secured around the vessel and the inserted cannula to prevent to vessel from sliding off. These larger, more rigid cannulas have a circumferential ridge behind which the tie is formed to help prevent the vessel from sliding off the cannula. This process is somewhat cumbersome
20 as it requires cannulation, stabilizing of the cannula within the vessel, and finally tying of a suture around the vessel and cannula. As the suture is being tied, the vessel can slide off the cannula and, therefore, an assistant must be used to hold the vessel and cannula stable.

When vessels are very small, such as in the range of 1 to 2 millimeters, very small cannulas 10 must be inserted into the vessel 12 (Figure 14). The walls of these small cannulas are very thin so that there is space for an infusion lumen 14. Also, there is no increased diameter portion or ridge on the cannula 10. For this reason, it is more difficult to hold the vessel 12 in place with a suture 16. The suture 16 must be tied quite tightly to hold the vessel 12 on the cannula 10. As the cannula 10 is thin, this frequently occludes the lumen 14 by crushing the cannula 10, as shown in Figure 1, and thereby prevents fluid flow. If the suture is tied too loosely, the vessel frequently slides off the cannula.

In view of these and other problems in this area, it would be desirable to provide a device that simplifies the attachment of a cannula to a vessel. Additional advantages would be obtained by eliminating the need for suture tying, increasing the speed of the procedure, and reducing the problems related to cannulating small vessels.

Temporary pacing wires are placed at almost every cardiac operation, but there have been no advances for many years. There are a number of current temporary pacemaker leads available for pacing after cardiac surgery. Leads (in reality a bare segment of an insulated wire) can be attached to the heart by a suture which holds the exposed wire in contact with the surface of the heart. When the lead is removed it is simply pulled out, breaking the stitch. The other way to attach the temporary lead is to attach a needle to the end of it and then pass the needle through the heart with a partial thickness bight. The needle is then

cut off the wire. Exposed wire is left in contact with the heart. The wire is removed by simply pulling it out. The wire often has a series of bends or a small amount of attached plastic material to increase the friction to keep it from coming out.

5 There are a number of problems with these two options.

Referring to Figure 20, the suture method requires that the surgeon place a stitch in the form of a loop 510 and then feed the wire 512 through the loop 510 and tie it. This is somewhat tedious, especially on a beating heart 514. The wire 512 under the suture loop to is often easily removed by
10 even a minimum of pull on the wire and it frequently has to be replaced. When a secure wire 512 is removed, there is the risk that the surface of the heart 514 will be torn as the suture snaps or that the suture does not snap and a small divot 516 of myocardium is pulled off as also shown in Figure 20. This can lead to bleeding which can be fatal.

15 The second system is shown in Figure 21 whereby a wire suture 520 is passed through the heart 514 is quicker. The wire suture 520 must be passed and the wire cut off as shown at cut 522 located above a flared stop portion 524. Flared stop portion 524 is designed to prevent the wire from being pulled back through heart 514. However,
20 during insertion the wire 520 frequently causes bleeding and the bleeders must be sutured. When the wire 520 is removed, there is a risk that the friction of the wire removal combined with the drag of the flared portion 524 will result in a piece of myocardium being torn, again resulting in

bleeding. Also, the wire 520 frequently becomes dislodged before the chest is closed and it has to be replaced.

The prior art does not demonstrate the concept of leaving a small permanent electrode in place and separating this from the wire. This concept is very important because on removal the risk of bleeding comes when the wire is pulled through the heart muscle or when the suture must snap.

In short, current methods are somewhat tedious, can result in bleeding at insertion and removal and the leads frequently become dislodged requiring complete reinsertion. It would be very useful to ease the insertion, permit reattachment should the wire become dislodged and reduce the risk of bleeding when the wire is removed.

Summary of the Invention

The present invention generally provides apparatus directed at solving problems, such as those described above, with regard to replacing a heart valve within a vessel. In one general aspect, the invention provides a replacement heart valve and a plurality of temporary commissure stabilizers. More particularly, the replacement heart valve will generally have an annular base and a plurality of spaced apart commissures extending from the annular base at spaced apart positions. The valve may be formed of animal tissue, such as valves harvested from pigs, cows or human donors. Optionally, the valve may be formed from synthetic, biologically compatible material. With the typical aortic valve replacement, there will be three commissures spaced

roughly 120° apart. Each commissure includes a proximal end connected with the annular base and an opposite distal end. The plurality of commissure stabilizers are connected to the commissures in a removable manner. These commissure stabilizers position and stabilize the commissures of the replacement heart valve as a surgeon secures the replacement heart valve in place within the vessel. The commissure stabilizers, in the instance of an aortic valve replacement, positively orient the commissures at the 120° spaced apart positions and generally perpendicular to a plane which contains the annular base of the heart valve.

Following securement of the replacement heart valve within the vessel, the commissure stabilizers are preferably removed to avert the various disadvantages of permanent stents or frames. However, there may be situations in which a particular surgeon desires to leave one or more of the commissure stabilizers in place and the invention advantageously provides for this option as well. In the preferred embodiment, the commissure stabilizers are connected together at spaced apart distal positions, for example, by a generally annular member. Each commissure stabilizer preferably comprises at least one elongate member attachable in a manner allowing removal from the distal end of the respective commissure following implantation of the heart valve.

The replacement heart valve can include respective receiving elements for the commissure stabilizers. These may comprise pockets, loops or other structure adapted to receive the stabilizers in a manner allowing removal by a surgeon at the distal end of the commissures after

implantation. The commissure stabilizers may also be removably affixed to other supporting structure, such as the generally annular member described above. This, for example, will allow the surgeon to remove the annular member or other supporting structure for easier suturing access, while at least temporarily leaving the commissure stabilizers in place for positioning purposes. After suturing and/or other securement of the valve, the commissure stabilizers would be removable to achieve the full advantages of this invention.

Each commissure stabilizer may further comprise at least two spaced apart elongate members or, more preferably, three elongate members. One or more of these members may curve or flare outwardly in a lengthwise direction to urge the commissures of the replacement heart valve against the flared interior wall of the vessel. The outer elongate members may also angle or curve away from the central elongate member to extend along opposite edge portions of the respective commissures.

In another aspect of the invention, the positioning and stabilizing device may be formed in a collapsible manner allowing insertion into the vessel in a collapsed state and subsequent expansion for positioning and stabilizing the valve commissures during securement of the valve within the vessel. For example, the positioning and stabilizing device may be at least partially formed of a shape memory material allowing the positioning device to be collapsed and expanded as necessary. This aspect of the invention may also be practiced in other manners, such as through the use of hinged or otherwise collapsible and expandable structures.

In accordance with another aspect of the invention, a flexible material may connect the distal ends of the three commissures. This will prevent the commissures from moving radially apart due to late sinotubular enlargement. This material may also be secured to the internal wall of the vessel to help prevent the need for reoperation due to the complications of late enlargement of the sinotubular junction as described above.

A method of implanting a replacement heart valve in accordance with the invention includes inserting the replacement heart valve into a patient, connecting at least one commissure stabilizer to each of the commissures of the replacement heart valve either before or after inserting the replacement heart valve, securing the replacement heart valve within the patient using the commissure stabilizers to orient the commissures of the replacement heart valve, and removing one or more of the commissure stabilizers from the patient leaving the secured replacement heart valve in place. Other methods of utilizing apparatus as described herein are also within the scope of this invention as will be apparent.

According to another aspect of the invention, a cannula is placed in a vessel and tied with a suture tight enough to prevent leaking between the vessel and the cannula, but loose enough to prevent occluding the lumen of the cannula. A hub of the cannula contains a friction lock so that the suture which holds the vessel on the cannula may be retained by the friction lock thereby preventing the vessel from sliding off the cannula. The friction lock may be substituted with other retaining members for the suture.

In another embodiment, tying a suture to the vessel is eliminated, for example, through the use of a clamp having movable jaws. The vessel engaging portions of the jaws may be covered with a soft material, such as foam, for protecting the vessel. The jaws may be moved between opened and closed positions. The cannula is inserted in the vessel and the jaws are moved over the vessel containing the cannula. The jaws are then moved from the open position to the closed position. This seals the vessel to the cannula and prevents the vessel from sliding off the cannula. This embodiment is presently preferred because it is quicker and applies to small or large vessels. There is also no need for a ridge or area of increased diameter on the cannula. Also, fine cannulas would not be crushed and no assistant is necessary as one hand may hold the cannula and vessel together, while the other hand may be used to open and close the jaws. Finally, the device would be inexpensive and simple to manufacture.

The invention further contemplates a temporary pacing wire system which eliminates the risk of bleeding from the heart when the lead is attached. It is another object of this invention to demonstrate a temporary pacing lead which can be removed from the heart without the risk of bleeding from the heart. It is another object of this invention to demonstrate a temporary pacing lead which can be re-attached should it be inadvertently removed from the heart before the incision is closed. It is a further object of this invention to describe a temporary pacing system lead that can be quickly attached to the heart without need for suture.

An electrode is permanently attached to the heart. The electrode can be a very tiny piece of metal, such as a clip. Releasably attached to the electrode is a wire which can be removed from the electrode and reattached to it. The electrode does not cause bleeding on attachment to the heart. The electrode is not removed from the heart, so that when the wire is pulled there is no ripping of the heart tissue but only separation of the electrode from the wire. Should the wire be inadvertently removed from the electrode after it is attached it is possible to quickly reattach it.

10 The electrode could be sutured to the heart. More simply and more efficient would be a mechanically applied electrode clip. Clips can be applied in seconds and do not require suture. The clip could take the form of a current vessel ligation clip. Alternatively, specially modified clips for attachment could include an extension attached to a hemoclip which
15 impales the heart. Another variation could include a clip that looks like a scorpion's pincer.

 The attachment of the wire to the clip can be accomplished in a number of ways. The clip could have a small loop through which a loop of preformed pacing wire is attached. The loop on the pacing wire could
20 open to ensure easy removal. The clip could have two parallel rabbit ear-like attachments for holding the wire in place. Many other attachments would be possible to configure.

 There are multiple advantages to the invention. For example, no suturing is required with a clip-on electrode. The clip is attached by

simply squeezing the handle of a small tool. The wire is preattached to the clip so that there is an instantly functioning pacemaker with no additional steps.

5 The pacing wire is attached reversibly to the electrode clip so that it can be easily pulled out without the risk of tearing myocardium. This is due to the fact that the clip is permanently attached to the heart and the wire slips away from or disengages the clip. There would be no direct dislodgement from the heart.

Should the wire become accidentally dislodged during surgery, it
10 can be easily reattached.

The product is easy to manufacture, package and distribute as it may take the form of existing hemoclip products.

These and other objects, advantages, and features of the invention will become more readily apparent to those of ordinary skill in the
15 art upon review of the following detailed description of the preferred embodiments, taken in conjunction with the accompanying drawings and as more generally set forth in the appended claims.

Brief Description of the Drawings

Figure 1 is a partially fragmented perspective view of an aorta
20 undergoing a valve replacement operation with an unstented biologic replacement valve in the process of insertion;

Figure 2 is a view similar to Fig. 1, but showing the initial removable attachment of a positioning and stabilizing device having

commisure stabilizers constructed in accordance with one embodiment of the invention;

Figure 3 is a perspective view similar to Fig. 2, but showing the positioning and stabilizing device fully inserted and the properly positioned and stabilized commisures being sutured in place;

Figure 4 is a perspective view similar to Fig. 3, but showing the fully implanted heart valve;

Figure 4A is a cross sectional view taken along line 4A-4A of Fig. 4;

Figure 5 is a perspective view showing an alternative embodiment of a positioning and stabilizing device being removed from a replacement heart valve following implantation;

Figure 6 is a perspective view of another alternative positioning and stabilizing device constructed in accordance with the invention;

Figure 6A is a cross sectional view taken along line 6A-6A of Fig. 6;

Figure 7 is a perspective view of another alternative embodiment of a positioning and stabilizing device;

Figures 8A and 8B are perspective views of another alternative positioning and stabilizing device respectively shown in collapsed and expanded conditions;

Figure 9 is a perspective view of an alternative replacement heart valve and removable positioning and stabilizing device constructed in accordance with the invention;

Figure 9A is a perspective view of the apparatus shown in Fig. 9 with the positioning and stabilizing device removed;

Figure 9B is a fragmented and enlarged view of the positioning and stabilizing device of Figs. 9 and 9A showing the separable parts thereof;

Figure 10 is a perspective view of another alternative replacement heart valve and removable positioning and stabilizing device constructed in accordance with the invention;

Figure 11 is a perspective view of an aortic expansion device constructed in accordance with the invention;

Figure 12 is a perspective view of an alternative aortic expansion device;

Figure 13A is a top view of the expansion device illustrated in Figure 12, but shown in a collapsed condition; and

Figure 13B is a top view of the expansion device shown in Figure 12 in an expanded condition.

Figure 14 is a fragmented, partial cross sectional view of a prior art cannulating device.

Figure 15 is a fragmented, partial cross sectional view of a cannulating device constructed according to one embodiment of the invention.

Figure 15A is an enlarged view of encircled portion 15A of Figure 15.

Figure 16 is a fragmented, partial cross sectional view of a cannulating device constructed in accordance with another embodiment of the invention.

Figure 17 is a fragmented, elevational view of the device shown in Figure 16, but showing an elastic ligature forcing a pair of clamping jaws into a closed position.

Figure 18 is an elevational view of an alternative embodiment similar to Figure 17, but showing the ligature in a disengaged position holding the jaws in an open position.

Figure 19 is a cross sectional view taken along line 19-19 of Figure 17.

Figure 20 is an elevational view showing a prior art method of attaching and removing a temporary pacing wire to the heart of a patient;

Figure 21 is an elevational view similar to Figure 20, but showing an alternative prior art method of attaching a temporary pacing wire to the heart;

Figure 22 is a perspective view of a temporary pacemaker lead constructed in accordance with one embodiment of the invention;

Figure 23 is a perspective view showing the temporary pacemaker lead of Figure 22 attached to the heart of a patient;

Figure 24 is a perspective view of one alternative embodiment of the invention;

Figure 25 is a side elevational view of the embodiment shown in Figure 24; and

Figure 26 is a perspective view of another alternative embodiment of the invention.

5 **Detailed Description of the Preferred Embodiments**

Figure 1 illustrates an aorta 10 which a surgeon has incised to create an opening 12 after a patient has been placed on a heart-lung machine. One or more retractors 14 may be used by assistants to gain access to opening 12. Aorta 10 may be partially incised as shown or it
10 may be fully incised across its transverse dimension. During this procedure, the patient's heart 16, disposed below the surgical site, is normally in an arrested state due to the use of the heart-lung bypass machine and cardioplegia.

An unstented replacement valve 20 is further shown within
15 aorta 10 in an initial flimsy, unsupported condition. In this case, a fabric covering 22 is stitched on the outside of the biologic tissue 24, which may be human or other animal tissue or synthetic material. Replacement valve 20 comprises typically three commissures 26, 28, 30 extending from an annular base 32. Replacement valve 20 has been inserted within aorta 10
20 such that annular base 32 is disposed at the annulus 34 of aorta 10. Conventional sutures 36 may be used as shown to pull replacement valve 20 within aorta 10 until it resides on annulus 34 in a known manner.

As further shown in Figure 4A, a plurality of sutures 54 are typically placed around the annular base 32 and into annulus 34.

Replacement valve 20 must be disposed within aorta 10 so as not to occlude orifices 38, 40 communicating with the left and right coronary arteries (Figure 2). As additionally shown in Figure 4A, the typical aortic replacement valve includes three cusps 42, 44, 46, respectively connected with the three commissures 26, 28, 30 for movement between open and closed positions as the heart beats to pump blood into the aorta. Sealing lines of contact 48, 50, 52 are formed between the respective cusps 42, 44, 46. To maintain an effective seal along lines 48, 50, 52, commissures 26, 28, 30 must be positioned and secured within aorta 10 in a precise manner. In this regard, each commissure should preferably extend in a relatively perpendicular, non-skewed manner along the interior aortic wall 10a, and in a manner that is essentially perpendicular to annular base 32. If this is not done, strain will be placed on commissures 26, 28, 30 and an effective seal between cusps 42, 44, 46 may eventually be lost. Undue strain on commissures 26, 28, 30 can cause decay and calcification and eventually lead to valve failure and either death or a second surgical operation.

Figures 2 and 3 illustrate one embodiment of a positioning and stabilizing device 60 constructed in accordance with the invention. Generally, positioning and stabilizing device 60 may be used in a temporary manner while securing commissures 26, 28, 30 to aortic wall 10a. Positioning and stabilizing device 60, in this embodiment, includes an

annular portion 62 connected with a plurality of stabilizers 64, 66, 68, each taking the form of a single elongate member. Each stabilizer 64, 66, 68 preferably bows outwardly along its length so as to generally conform to a flared region 70 of the aortic root. As one of many possible temporary

5 securement methods, each stabilizer 64, 66, 68 is slipped between fabric covering 22 and biologic tissue 24 of replacement valve 20. In the case of a valve which does not have a fabric covering, other securing structure such as suture loops, hooks, etc., may be used to attach stabilizers 64, 66, 68. This temporary connection may be made before replacement valve 20

10 is inserted into aorta 10 or after valve 20 is inserted within aorta 10. In the preferred embodiments, assembly of a positioning and stabilizing device and replacement valve, such as device 60 and valve 20, is felt to be best accomplished prior to surgery to allow for insertion as a unit. As shown in Figure 3, once replacement valve 20 and positioning and stabilizing device

15 60 have been secured within aorta 10, with stitches 54 already placed at annulus 34, suturing of commissures 26, 28, 30 can begin. This may be accomplished using a typical needle 72 and suturing thread 74 manipulated by a gripping implement 76. The surgeon places sutures 78 in this manner along the entire periphery of each commissure 26, 28, 30. It will be

20 appreciated that other manners of securing replacement valve 20 to aorta 10 may be used in accordance with the invention and, for example, include gluing, stapling or other mechanical fasteners. Figure 4 illustrates the completely secured replacement valve 20 implanted within aorta 10. It will be appreciated that, in this embodiment, once positioning and stabilizing

device 60 has been removed from the pockets formed between fabric covering 22 and biologic tissue 24, the distal ends 26a, 28a 30a may be stitched to the aortic wall 10a.

Figure 5 illustrates one alternative embodiment of a replacement valve 20' useful in accordance with the invention.

Replacement valve 20 includes pockets 80 on the outside of each commissure 26, 28, 30 for receipt of an alternative positioning and stabilizing device 90. Like the first embodiment, positioning and stabilizing device 90 can include an annular portion 92 and a plurality of three stabilizers 94, 96, 98. In this embodiment, each stabilizer further comprises multiple elongate members adapted to be removably inserted within pockets 80. More specifically, each stabilizer 94, 96, 98 comprises respective elongate members 94a-c, 96a-c and 98a-c. As will be appreciated from stabilizer 96, outer elongate members 96a, 96c curve outwardly from the middle elongate member 96b. In this manner, outer members 96a, 96c extend within respective pockets 80 along the outer curved edges 28b, 28c of commissure 28. The remaining stabilizers 94, 98 function in a similar manner. It will be further appreciated that each stabilizer 94, 96, 98 bows outwardly, as in the first embodiment, to conform to the flare 70 at the aortic root. Stabilizers 94, 96, 98 are flexible enough to be withdrawn, as shown in Figure 5, from pockets 80 after suturing of each commissure 26, 28, 30 as previously described. Positioning and stabilizing device 90 may be formed from various materials

and in various configurations for this purpose. These may include metals, super elastic alloys, or plastics.

Figures 6 and 6A illustrate another alternative positioning and stabilizing device 100 constructed in accordance with the invention. In this embodiment, an annular portion 102 is removable from a plurality of
5 commisure stabilizers 104, 106, 108. In this manner, positioning and stabilizing device 100 may be used as described above with respect to devices 60 and 90, except that annular portion 102 may be removed for easier suturing access or other securement access when securing
10 commisures 26, 28, 30 (Figure 4) to aortic wall 10a. One of many possibilities for facilitating this function is shown in Figure 6 and Figure 6A in the form of connectors 110, 112, 114. Each of these connectors may receive a stabilizer 104, 106, 108 in a removable fashion with a slight interference fit. As best shown in Figure 6A, an end portion 104a of
15 stabilizer 104 may be received with a slight interference fit against a resilient tab 116. The other stabilizers 106, 108 may have a similar structure, as exemplified by end 108a shown in Figure 6. Many other fastening structures are possible other than this schematically illustrated example.

20 Figure 7 illustrates another alternative positioning and stabilizing device 120 having a generally similar construction and function to device 90 shown in Figure 5. Device 120 may be formed from a single length of wire, for example, and includes portions 122, 124, 126 analogous to the previously described annular portions. A connector 128

may be provided to connect opposite ends of the wire. Stabilizers 130, 132, 134 are formed with three sections each for purposes previously described in connection with Figure 5. These sections 130a-c, 132a-c, 134a-c serve similar functions to position and stabilize the commissures of a replacement heart valve, and device 120 may be removed from the heart valve in previously described manners.

Figures 8A and 8B illustrate another alternative positioning and stabilizing device 140 constructed from a shape memory material such as Nitenol. As shown in Figure 8A, device 140 may be collapsed in each a detached form with respect to a heart valve, as shown, or while connected to a replacement heart valve for insertion within the patient's aorta as a unit. Upon the application of heat or electric current once inserted within the aorta, device 140 expands to the position shown in Figure 8B and may then be used as previously described to position and stabilize the heart valve commissures during implantation. As shown in Figures 8A and 8B, one illustrative example of this device also includes an annular portion 142 and respective three-legged commissure stabilizers 144, 146, 148.

Figures 9 and 9A illustrate another heart valve replacement apparatus 160 constructed in accordance with the invention. In this embodiment, a replacement heart valve 162 may include a flexible material 164, optionally part of the fabric covering 166 of valve 162, which secures the three commissures 168, 170, 172 together at their respective distal ends 168a, 170a, 172a. It will be appreciated that flexible material 164 may be stitched to the interior aortic wall in conjunction with commissures

168, 170, 172. Thus, material 164 will prevent distal ends 168a, 170a, 172a from expanding away from one another as occurs during late sinotubular enlargement of the aorta. Therefore, this prevents valve failure as a result.

5 As further shown in Figures 9, 9A and 9B, an alternative embodiment of a positioning and stabilizing device 180 includes an annular portion 182 constructed from separate sections 182a, 182b, 182c, and a plurality of three stabilizers 184, 186, 188. Stabilizer 184, 186, 188 again are shown as three-legged structures for purposes previously described. In
10 this embodiment, however, stabilizers 184, 186, 188 are retained within loops 190, which may be suture loops sewn into fabric 166. It will be appreciated that other types of retaining structure may be used to at least temporarily retain stabilizers 184, 186, 188. In this embodiment, connectable end portions 192, 194, formed respectively as male and
15 female portions, may be used to make various connections and disconnections on device 180. For example, lower ends of adjacent stabilizers 184, 186, 188 may be connected at a junction 196 as shown in Figure 9. This may provide more consistent support along the edges of commissures 168, 170, 172. As further shown in Figure 9B, stabilizers
20 184, 186, 188 may be completely disconnectable from annular portion 182 while also allowing selective disconnection of sections 182a, 182b, 182c. This may be accomplished through the use of connecting elements 198 having respective female connecting portions 198a for engaging male connecting portions 192. It will be understood that many alternative

connectors and structures may be substituted for those shown while retaining the basic function and general concepts expressed herein.

Figure 10 illustrates a heart valve replacement apparatus 200 comprised a replacement heart valve 202, which may be formed from biological tissue or synthetic biologically compatible material. Heart valve 202 is again illustrated with three commissures 204, 206, 208, as is typical for replacement aortic valves. A positioning and stabilizing device 210 is fastened to the outside of valve 202, for example, by suture loops 211. This embodiment of the invention does not have any connection between the distal ends 204a, 206a, 208a of commissures 204, 206, 208 or at the distal end of positioning and stabilizing device 210. Also, in this embodiment positioning and stabilizing device 210 is formed in three sections 212, 214, 216 removably connected together at junctions 218, 220, 222. These connections may be similar to those shown in Figure 9B. Other types of connections may be used as well. Use of this embodiment of the invention will be similar to the previous embodiments, except that sections 212, 214, 216 may be removed individually from heart valve 202 following completion of its securement within the aorta. Sections 212, 214, 216 are preferably formed of a highly flexible plastic or metal which is biocompatible. This embodiment provides certain advantages, such as allowing one or more of the sections 212, 214, 216 to remain in place following surgery and providing additional room for a surgeon to access commissures 204, 206, 208 while suturing or otherwise securing commissures 204, 206, 208 to the aortic wall. It will be appreciated that

other configurations and numbers of legs and sections may be utilized by those of ordinary skill.

Figure 11 illustrates an expansion device 240 useful for expanding a vessel, such as the aorta, during valve replacement procedures. In this embodiment, expansion device may be formed as a collapsible and expandable structure, such as by being formed of shape memory material as described with respect to Figures 8A and 8B. It will be appreciated that Figure 11 shows the expanded condition only. Expansion device 240 may have three extensions 242, 244, 246 of a desired length for disposition between the respective commissures of an aortic replacement valve. Device 240 need not be attached to heart valve commissures, but may be used to expand the collapsed aorta to the proper flared shape thereby assisting the surgeon during a heart valve replacement procedure. This device overcomes the drawbacks of typical retractors which tend to distort the shape of the collapsed aorta and mislead the surgeon as to the correct position and orientation of the heart valve. Device 240 may be formed in various manners to be collapsible and selectively expandable, such as through the use of mechanically expandable portions or, preferably, expandable shape memory portions.

Figures 12, 13A and 13B illustrate an alternative collapsible and expandable retraction device 250. This device may be formed from a mesh or screen material and includes edge portions 252, 254 which allow expanding and contracting of the device. An upper end 256 is formed with a greater diameter than a lower end 258 in the expanded, operative

position shown in Figures 12 and 13B. This allows a surgeon to have greater access into and through the device to manipulate and, for example, suture a replacement heart valve in place below device 250 within the aorta. In use, and referring back to Figure 1, a surgeon will insert the

5 device 250 in the collapsed form shown in Figure 13A through opening 12 such that lower end 258 is situated within aorta 10 and upper end 256 is exposed. The surgeon will then allow device 250 to expand through its own resilience or through a shape memory property to the position shown in Figure 13B. Alternatively, other activation structure or means may be

10 provided for attaining the expanded condition. Once expanded, aorta 10 generally assumes a natural, pressurized shape allowing placement and implantation of replacement valve 20 in a more efficient and accurate manner. It will be understood that the expansion devices shown in Figures 11 through 13B are illustrated in the simplest currently contemplated

15 forms. It is further contemplated that additional handles or other support and actuation structure may be added while achieving the same general advantages of these embodiments.

Figure 15 illustrates another embodiment of the invention. Specifically, a cannulating device 320 is connected to a vessel 322 by

20 inserting a tube 324 containing a lumen 326 for introducing fluids into vessel 322. A suture 328 is tied around the outside of vessel 322, as shown, and has at least one end secured to a friction lock 332, as best shown in Figure 15A. Friction lock 332 may take many different forms, however, one simple form is the tab, as shown, with a knurled or

roughened undersurface 334 for retaining suture 328 in place and keeping vessel 322 from sliding off tube 324.

Figures 16-19 illustrate two additional and similar embodiments of a cannulating device 340, 340'. Like reference numerals refer to like structure in these embodiments. As shown in Figure 16, a cannulating device 340 is again shown as used on a vessel 342. A cannula or tube 344 of device 340 is inserted into vessel 342 and includes a lumen 346 for introducing fluids. A clamp 348 is secured to a hub 350 of device 340 and may take many different forms. In the embodiments shown, clamp 350 generally comprises a pair of jaws 352, 354. In the embodiment shown in Figures 17 and 18, a rubber ligature 356 may be used and moved from the position shown in Figure 18 to the position shown in Figure 17 to clamp jaws 352, 354 against vessel 342. Ligature 356 may be retained in respective recesses 358, 360 when jaws 352, 354 are in the closed position. Each jaw 352, 354 includes a respective semi-cylindrical jaw portion 362, 364 for partially encircling vessel 342 as best shown in Figure 19.

As further shown in Figures 16-18, devices 340 and 340' may be easily manipulated between open and closed positions by way of handles 366, 368, which may form part of jaws 352, 354 and which are secured to hub 350 by way of pivot connections 370, 372. It will be appreciated that various other retaining members and clamps may be used and, as more specifically related to the embodiments shown, other spring-biased mechanisms may be used to retain jaws 352, 354 in the closed

position. For example, one or more torsion springs (not shown) may be incorporated into the device 340 shown in Figure 16 to normally bias jaws 52, 54 into a closed position.

Additional aspects of the invention are apparent from Figures 17 and 18. Specifically, with ligature 356 engaged as shown in Figure 17, jaws 352, 354 are biased into a normally closed position as shown in solid lines. However, the user may squeeze handles 366, 368 together, as shown in phantom lines. This allows repositioning of device 340' or handles 366, 368 may be squeezed in this manner while initially attaching device 340' to vessel 342. As further shown in Figure 18, ligature 356 may be moved to a rearward position to hold jaws 352, 354 in an open position. This holds handles 366, 368 against hub 350. This may be used as an alternative manner of initially inserting tube 344 (Figure 16) into vessel 342. Once inserted, ligature 356 may be moved into recesses 358, 360 or 359, 361. As further shown in Figure 18, multiple sets of recesses 358, 360 and 359, 361 may provide different degrees of clamping force. In this illustrative example, recesses 359, 361 will provide greater clamping force as they are a greater distance apart.

Figures 22 and 23 show another embodiment of the invention. The electrode comprises a clip 430 which can be pinched onto the heart 432 (Figure 23) for quick attachment with a clip applier. There will be no bleeding since there is no hole and tissue is merely pinched. The electrode 430 is attached to a wire 434 in a releasable manner. This may be accomplished with engageable and disengageable loops 436, 438 as

shown. When the wire 434 is removed, the electrode stays on the heart and so there is no ripping of tissue.

Figures 24 and 25 show an alternate attachment of the wire 434 and an alternative electrode 440. This provides even less friction on removal. It is also easy to see that if the wire 434 comes free accidentally during surgery, it would be very easy to reattach. This is because of the frictional engagement members 442, 444. Figures 24 and 25 also show an electrode variation as mentioned above. In this embodiment, there is a spike 446 that impales the heart which is then squeezed on with a clip 10 applicator as with the first embodiment. This assures better contact with the heart muscle.

Figure 26 shows another way to attach an electrode to the heart with a scorpion-type pincer 450 that is pinched with a clip applicator. The sharp ends are squeezed together by the clip applicator. Another 15 alternative releasable electrode/wire link is shown. This again includes engageable and disengageable members 452, 454.

While the present invention has been illustrated by a description of a preferred embodiment and while this embodiment has been described in some detail, it is not the intention of the Applicants to restrict 20 or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The various features and concepts of the invention may be used alone or in numerous combinations depending on the needs and preferences of the user. This has been a description of the present invention, along

with the preferred methods of practicing the present invention as currently known. However, the invention itself should only be defined by the appended claims, wherein we claim:

1. Apparatus for replacing a heart valve within a vessel, the apparatus comprising:
 - a replacement heart valve having an annular base and a plurality of commissures extending from the annular base at spaced apart positions, each commissure having a proximal end connected with the annular base and an opposite distal end, and
 - a plurality of commissure stabilizers connected to the replacement heart valve in a removable manner, wherein the commissure stabilizers position and stabilize the commissures of the replacement heart valve as the replacement heart valve is secured within a vessel but are removable from the replacement heart valve following securement thereof within the vessel.
2. The apparatus of claim 1, wherein the commissure stabilizers are connected together at the spaced apart distal positions by a generally annular member and each commissure stabilizer further comprises at least one elongate member.
3. The apparatus of claim 2, wherein the three elongate members each curve outwardly in a lengthwise direction to urge the commissures of the replacement heart valve against an interior wall of the vessel.

4. The apparatus of claim 2, wherein the replacement heart valve includes respective receiving elements to removably receive the respective commissure stabilizers.
5. The apparatus of claim 4, wherein the receiving elements
5 further comprise pockets.
6. The apparatus of claim 4, wherein the receiving elements further comprise loops affixed to said commissures.
7. The apparatus of claim 2, wherein the commissure stabilizers are removably affixed to the generally annular member.
- 10 8. The apparatus of claim 2, wherein each commissure stabilizer further comprises at least two spaced apart elongate members.
9. The apparatus of claim 1, wherein each commissure stabilizer further comprises an elongate central member and a pair of elongate side members angled away from the elongate central member and extending
15 along opposite edge portions of the respective commissure.

10. The apparatus of claim 1, wherein the positioning and stabilizing device is formed in a collapsible manner allowing insertion into the vessel in a collapsed state and subsequent expansion for positioning and stabilizing the valve commissures during securement of the valve within
5 the vessel.

11. The apparatus of claim 11, wherein the positioning and stabilizing device is at least partially formed of a shape memory material allowing the positioning device to be selectively collapsed and expanded.

12. The apparatus of claim 1 further comprising a flexible material
10 connecting the distal ends of the three commissures.

13. The apparatus of claim 1, wherein said replacement heart valve is formed from animal or human tissue.

14. The apparatus of claim 1, wherein said replacement heart valve is formed from a synthetic biologically compatible material.

15 15. The apparatus of claim 1, wherein said commissure stabilizers are connected to the commissures of said replacement heart valve in a removable manner.

16. A replacement heart valve for implantation within a vessel, the replacement heart valve comprising:
- an annular base,
 - a plurality of commissures extending from the annular base at spaced apart positions, said commissures having proximal ends connected with said annular base and opposite distal ends, and
 - a flexible fabric material connecting the distal ends of said commissures and adapted to be secured to said vessel during implantation.
17. An expandable and collapsible vessel retraction device comprising:
- a body movable between expanded and collapsed conditions such that, in the collapsed condition the body may be inserted into an open vessel and actuated into the expanded condition whereby said vessel expands into a shape substantially corresponding to the natural pressurized shape of the vessel.
18. The vessel retraction device of claim 17, wherein the body is generally tubular.
19. The vessel retraction device of claim 17, wherein the body is at least partially formed of a shape memory material.

20. A method of implanting a replacement heart valve including an annular base and a plurality of commissures extending from spaced apart positions of the annular base, the method comprising:

5 inserting said replacement heart valve into a patient,
connecting at least one commissure stabilizer to each of said commissures of said replacement heart valve either before or after inserting said replacement heart valve,

securing said replacement heart valve within the patient using said commissure stabilizers to orient the commissures of the replacement heart valve, and

10 removing said commissure stabilizers from the patient leaving the secured replacement heart valve in place.

21. A method of implanting a replacement heart valve including an annular base and a plurality of commissures extending from spaced apart positions of the annular base, the method comprising:

15 connecting three commissure stabilizers of a positioning and stabilizing device to the respective three commissures of said replacement heart valve,

inserting said replacement heart valve into a patient,
20 securing said replacement heart valve within the patient using said commissure stabilizers to orient the three commissures of said replacement heart valve, and

removing said positioning and stabilizing device from the patient leaving the secured replacement heart valve in place.

22. A cannulating device comprising:

a hub portion;

5 a cannula extending from said hub portion and adapted to be inserted into a blood vessel; and

a retaining member extending from the hub portion and adapted to retain a suture tied around the blood vessel to prevent the blood vessel from slipping off the cannula.

10 23. The cannulating device of claim 22, wherein the retaining member is a frictional engagement member.

24 The cannulating device of claim 23, wherein the frictional engagement member includes a roughened surface for engaging the suture.

25. The cannulating device of claim 22, wherein a space is formed
15 between the hub and the retaining member for receiving and retaining the suture.

26. A cannulating device comprising:
a hub portion;
a cannula extending from said hub portion and adapted to be inserted into a blood vessel; and
5 a clamp coupled with the hub portion and adapted to retain the blood vessel in a sealed condition on the cannula.
27. The cannulating device of claim 26 further including a biasing mechanism operative to bias the clamp into at least one of an open position and a closed position with respect to the vessel.
- 10 28. The cannulating device of claim 27, wherein the biasing mechanism is an elastic ligature.
29. The cannulating device of claim 28, wherein the elastic ligature is adjustable to provide different degrees of clamping force.
30. The cannulating device of claim 26, wherein the clamp
15 includes jaws with semi-cylindrical portions for receiving the vessel.
31. The cannulating device of claim 26, wherein the clamp includes soft jaw portions for engaging the vessel.

32. A temporary pacemaker lead for connection with heart tissue of a patient, the temporary pacemaker lead comprising:
- a wire having an electrically conductive portion;
 - a first connector portion on the wire;
 - 5 an electrode having a second connector portion releasably engaged with said first connector portion so as to establish electrical conduction between the electrode and the electrically conductive portion of the wire, whereby said electrode may be affixed to the heart tissue and said wire may be releasably secured to the electrode by way of the first and
 - 10 second connector portions.
33. The temporary pacemaker lead of claim 32, wherein said first and second connector portions comprise engageable and disengageable loops.
34. The temporary pacemaker lead of claim 32, wherein the
- 15 connector portions each comprise frictionally engaging connector portions.
35. The temporary pacemaker lead of claim 34, wherein the second connector portion further comprises a pair of frictional engagement elements.
36. The temporary pacemaker lead of claim 32, wherein the
- 20 electrode further includes a spike portion for insertion into the heart tissue.

37. The temporary pacemaker lead of claim 32, wherein the electrode further comprises a pair of spike portions adapted to be moved together into the heart tissue.

38. A temporary pacemaker lead for connection with heart tissue
5 of a patient, the temporary pacemaker lead comprising:
a wire having an electrically conductive portion;
a first connector portion on the wire;
an electrode clip having a second connector portion releasably
engaged with said first connector portion so as to establish electrical
10 conduction between the electrode clip and the electrically conductive
portion of the wire, said electrode clip having at least one movable portion
allowing fixation of the clip to the heart tissue and wherein said wire may
be releasably secured to the electrode clip by way of the first and second
connector portions.

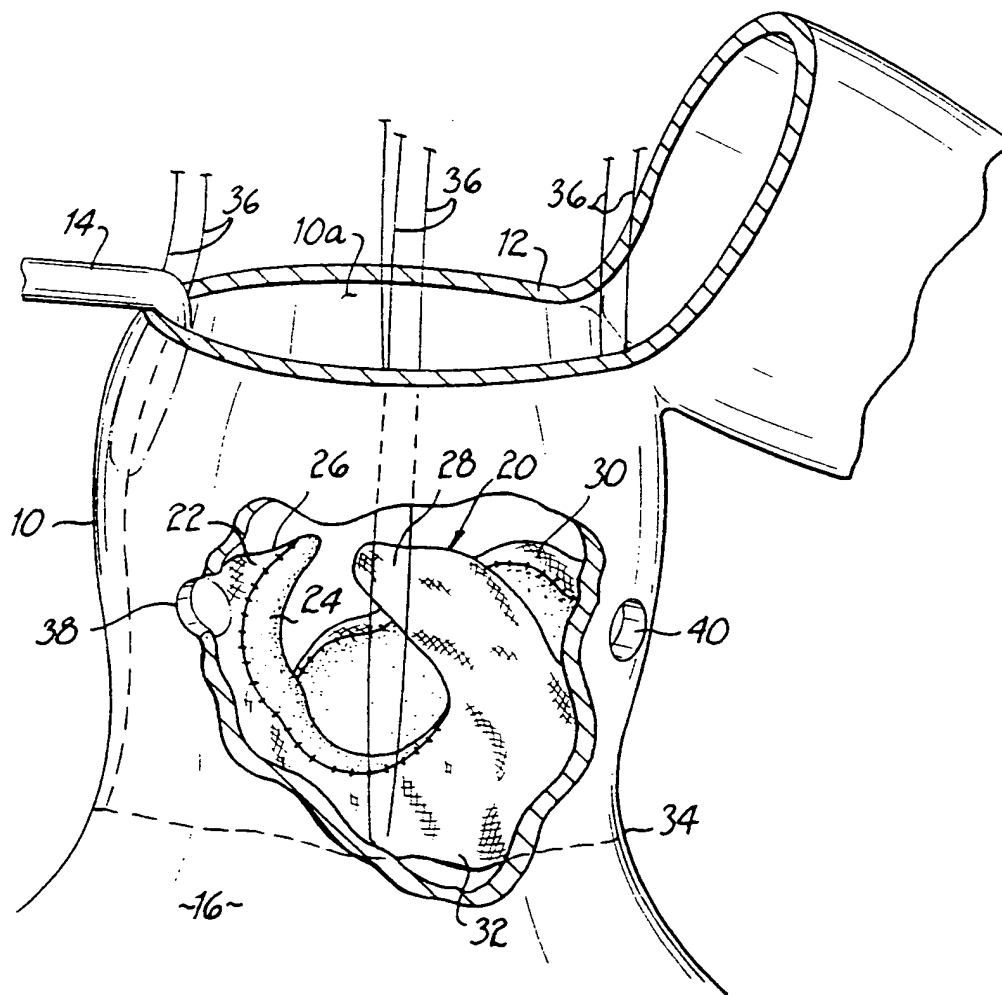


FIG.1

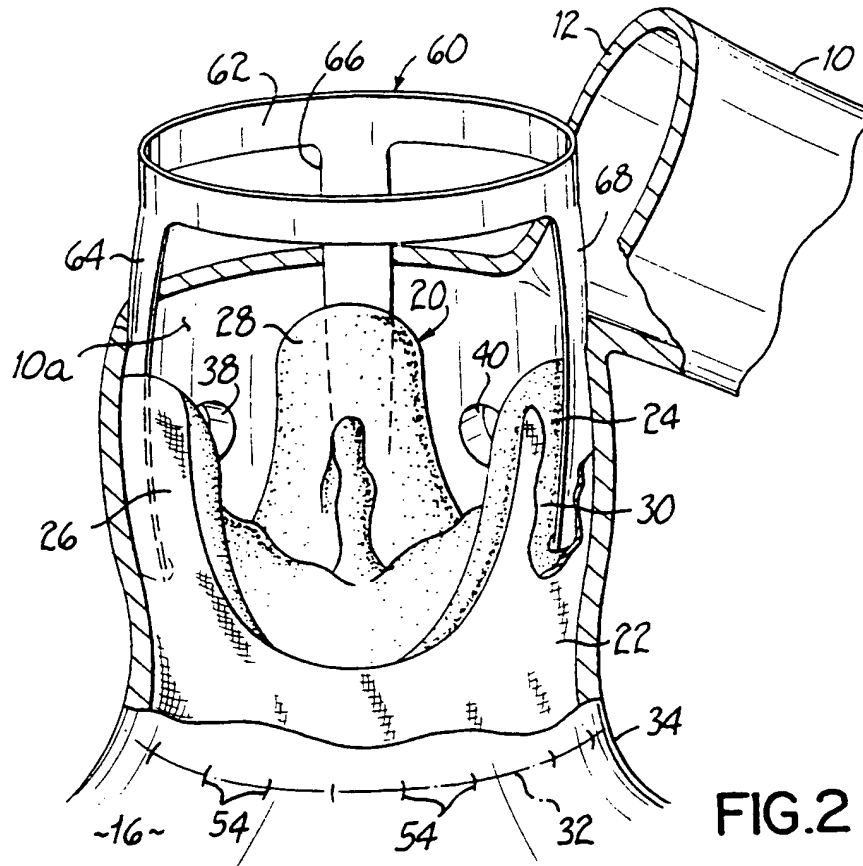


FIG. 2

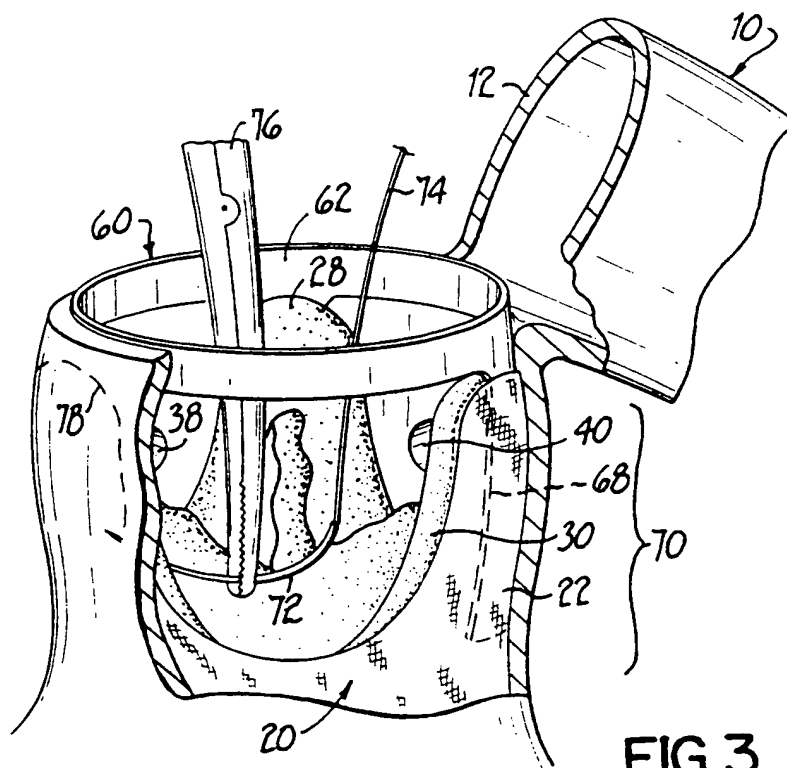


FIG. 3

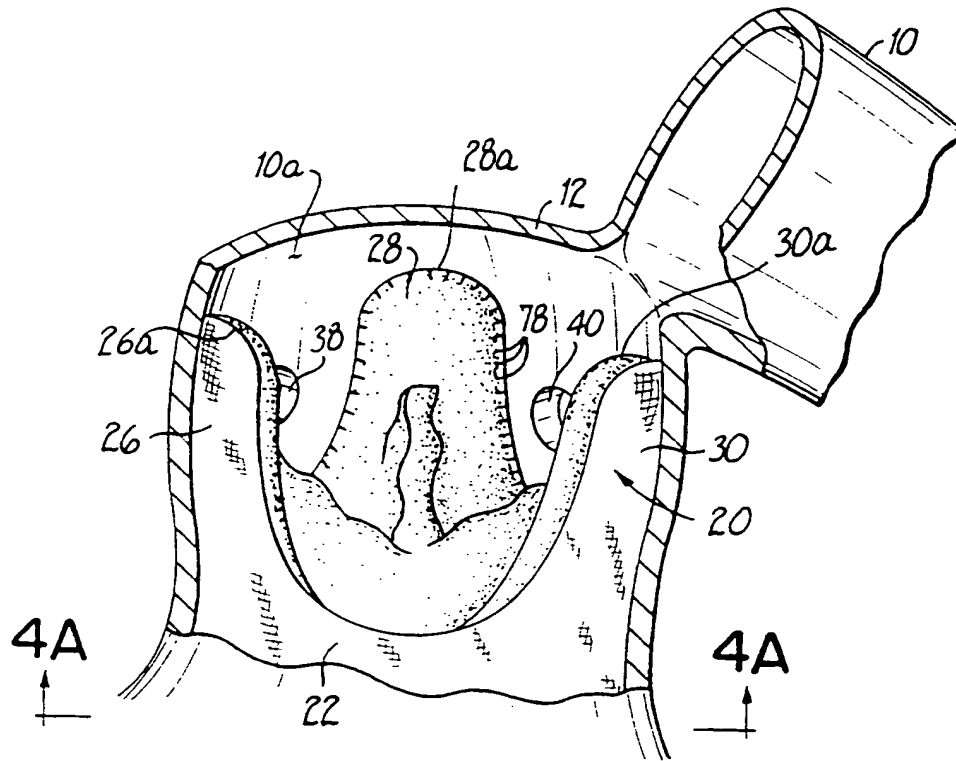


FIG. 4

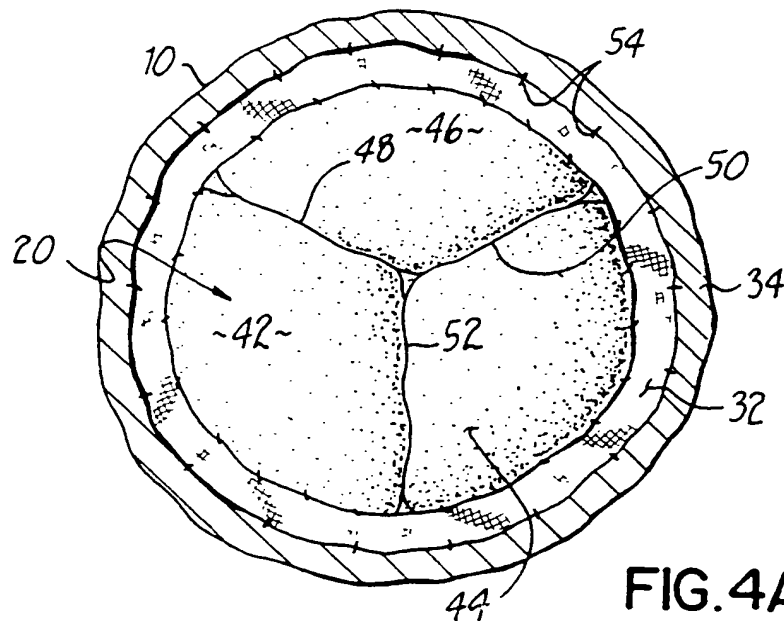
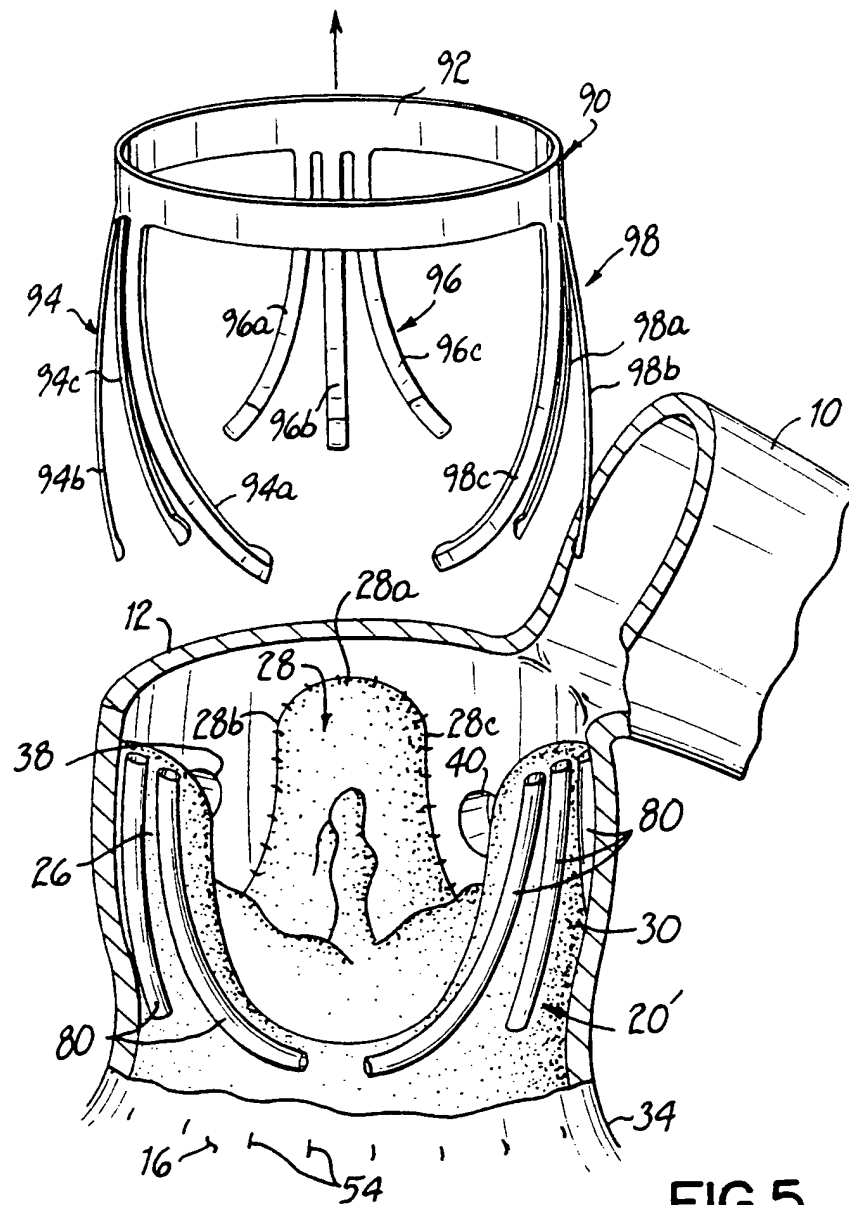
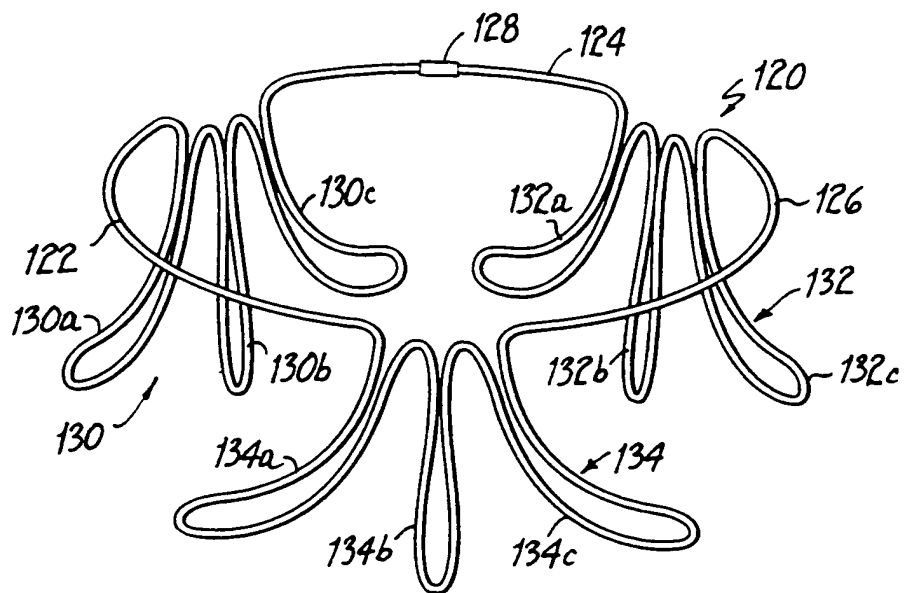
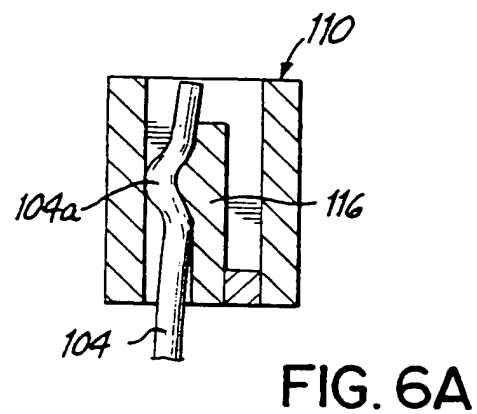
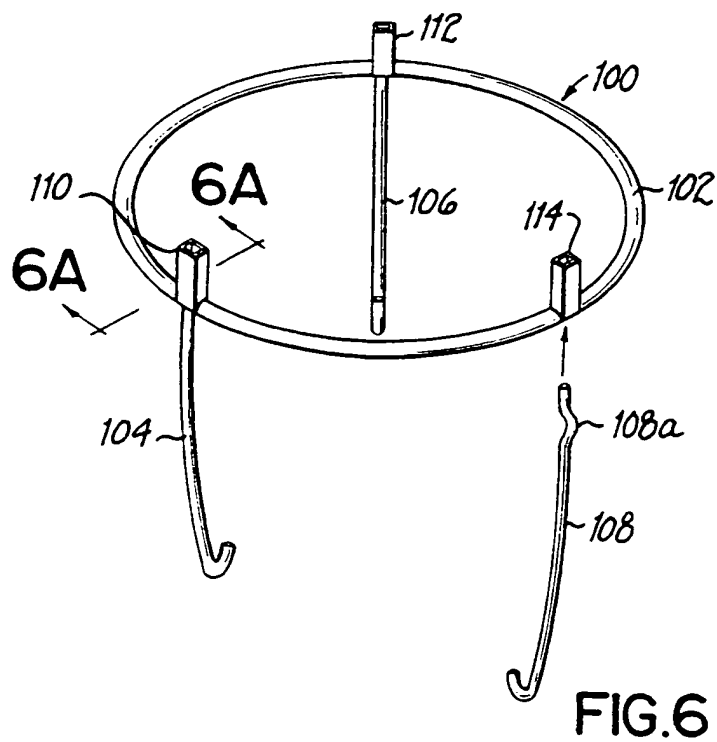


FIG. 4A





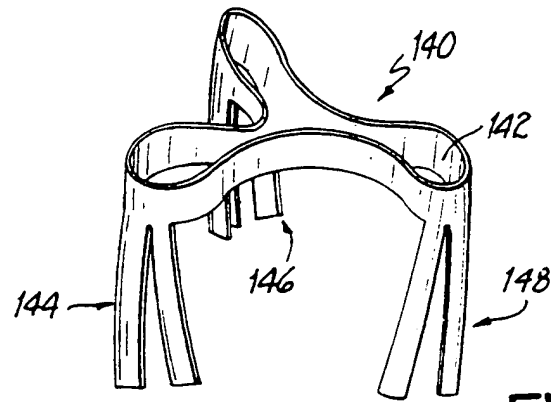


FIG. 8A

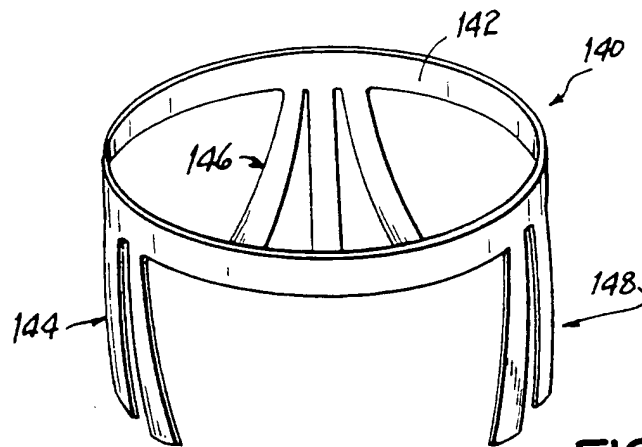


FIG. 8B

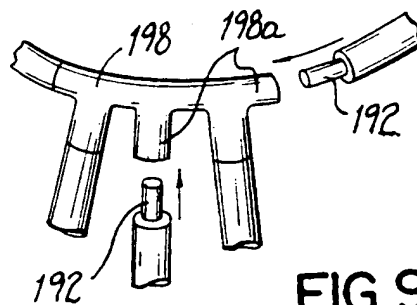


FIG. 9B

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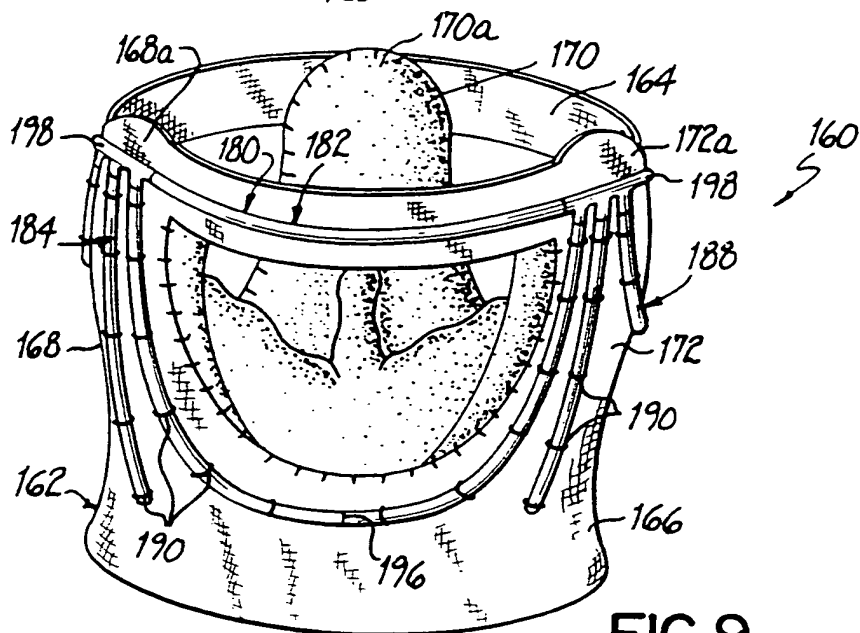


FIG. 9

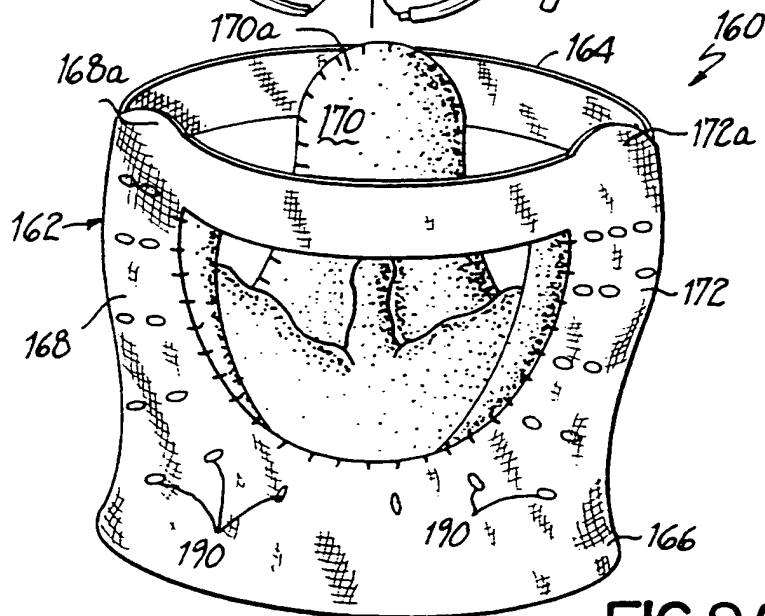
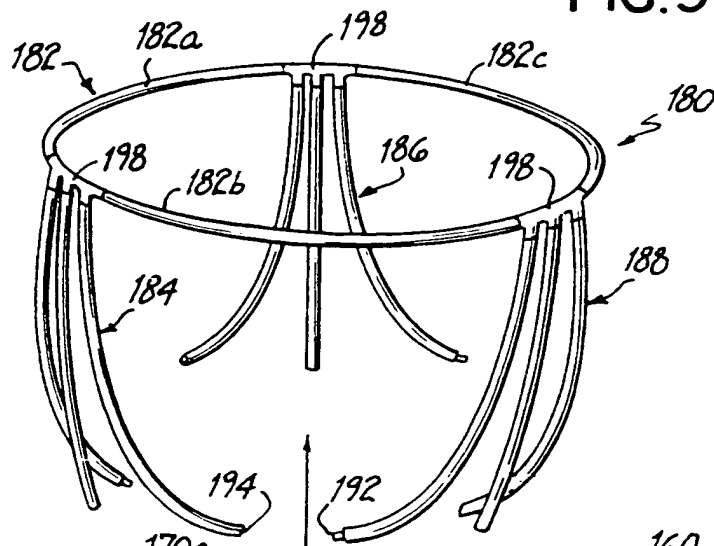


FIG. 9A

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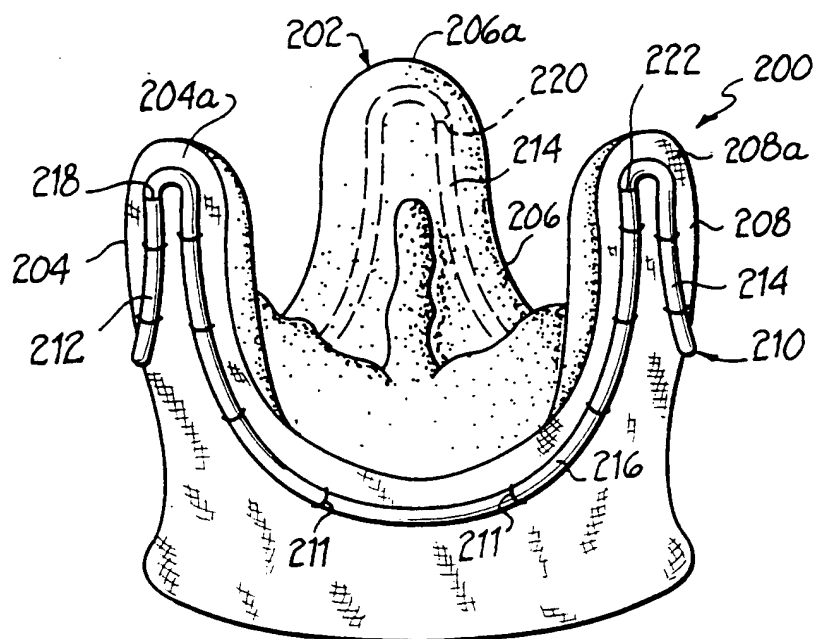


FIG. 10

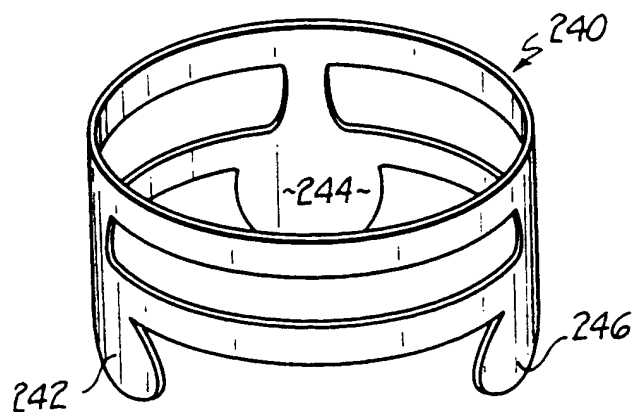
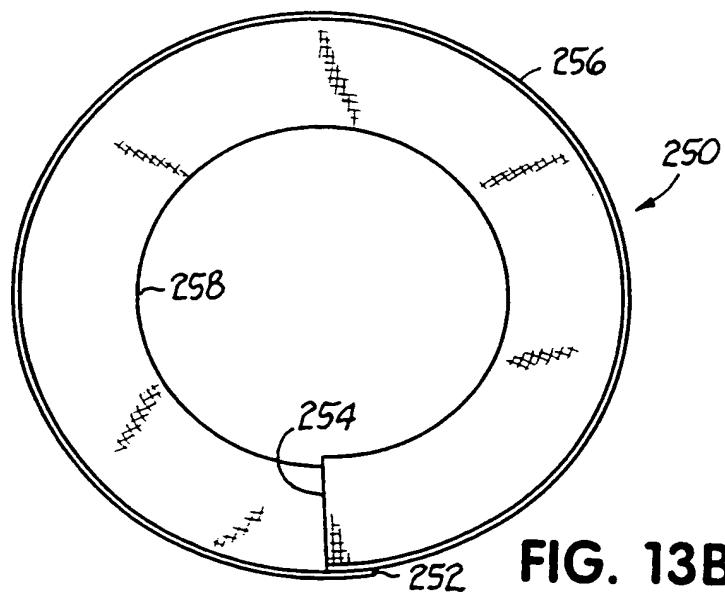
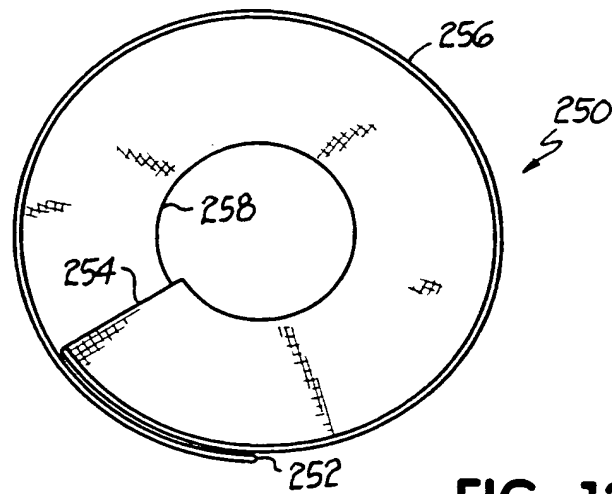
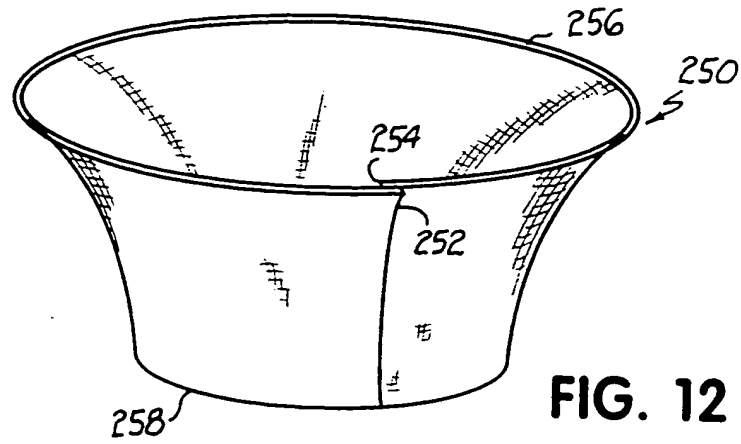
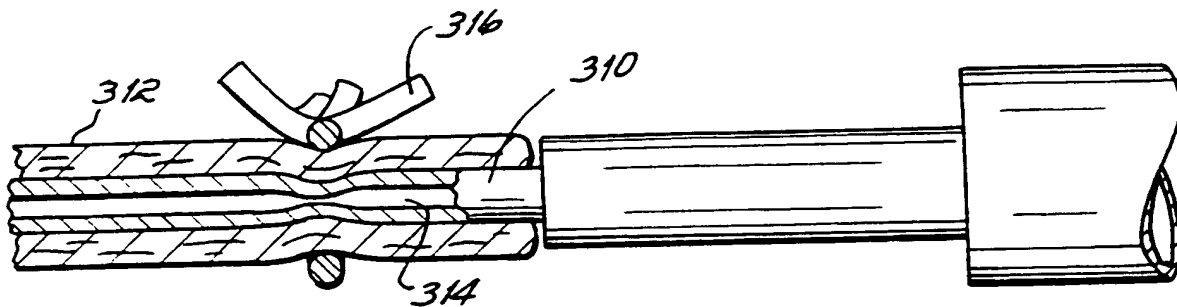


FIG. 11



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PRIOR ART
FIG. 14

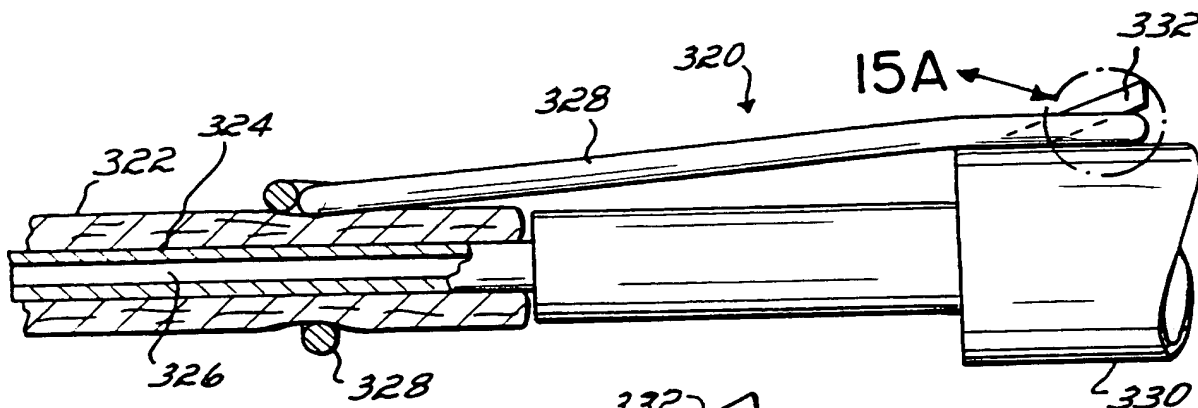


FIG. 15

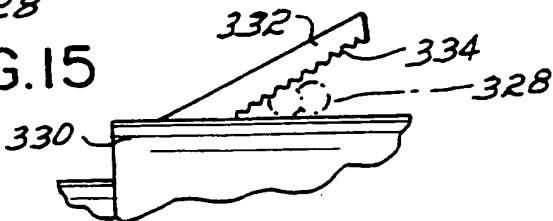


FIG. 15A

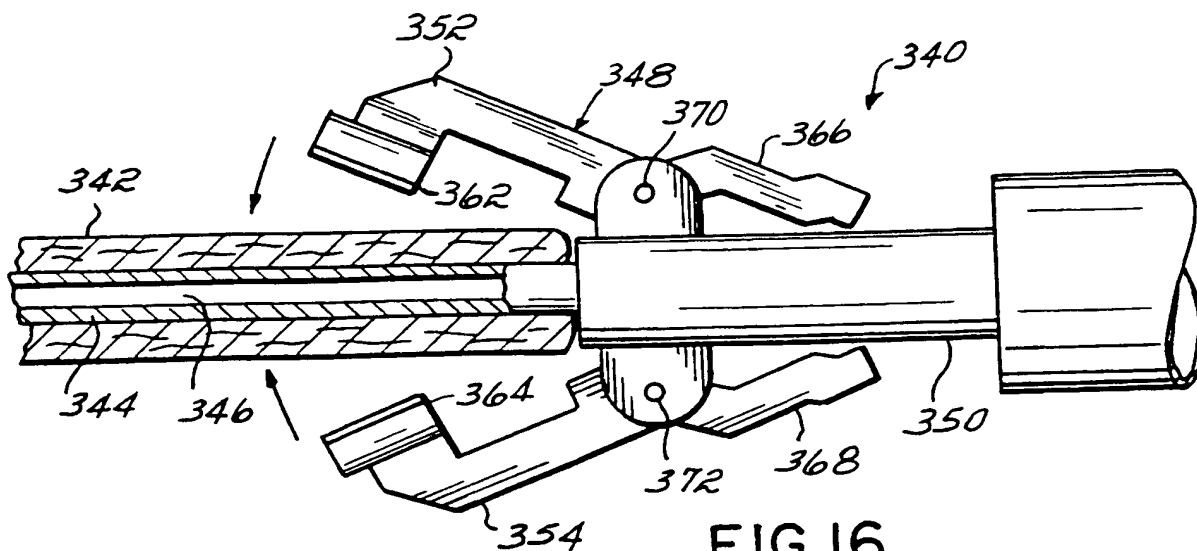


FIG. 16

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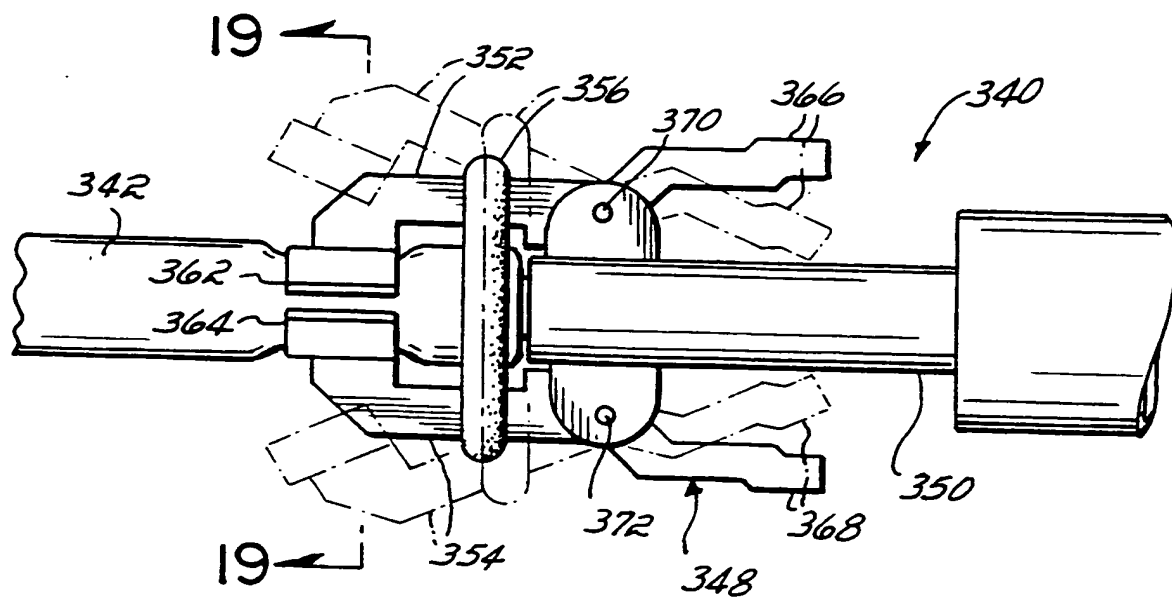


FIG. 17

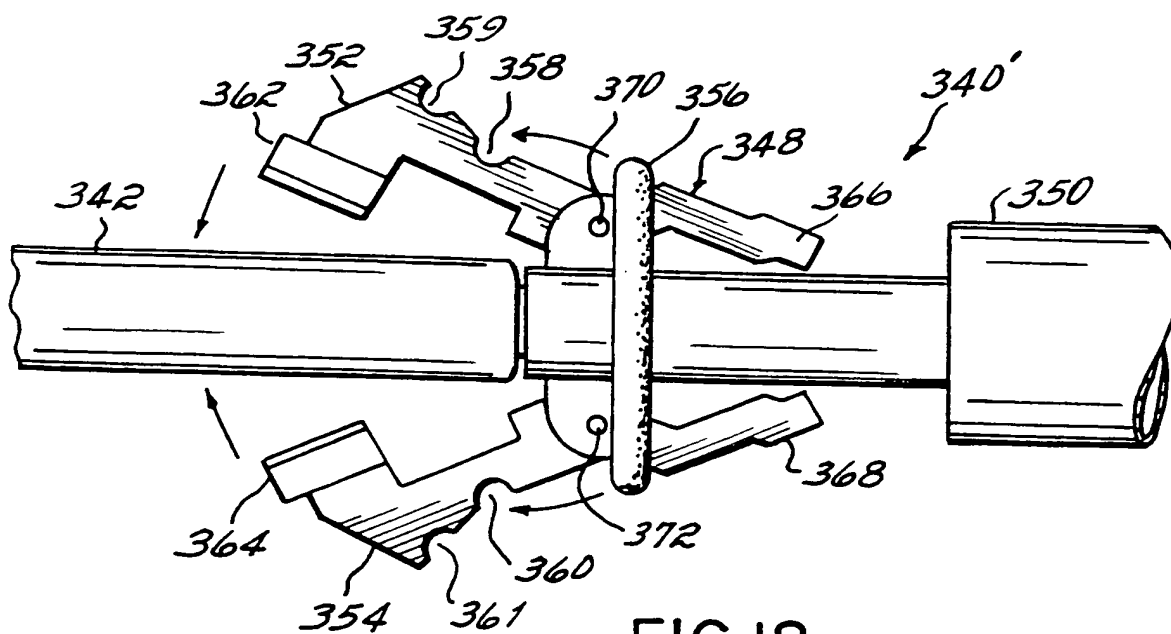


FIG. 18

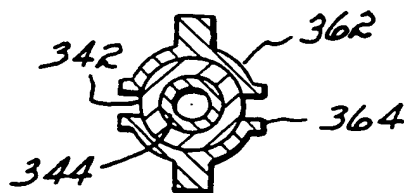
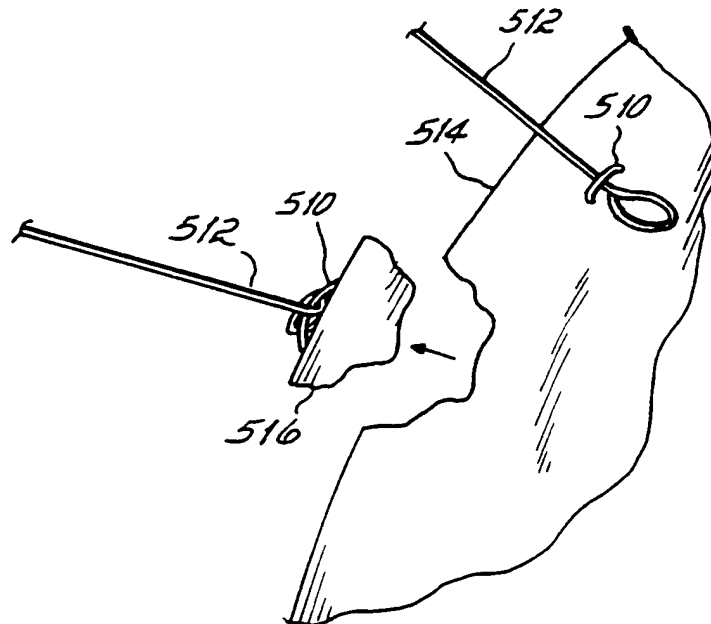
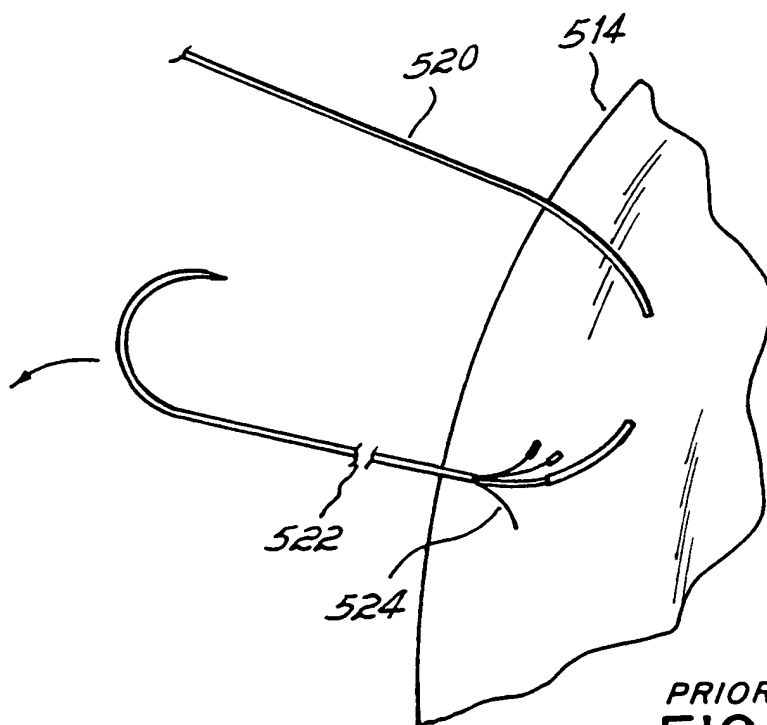


FIG. 19

SUBSTITUTE SHEET (RULE 26)



PRIOR ART
FIG.20



PRIOR ART
FIG.21

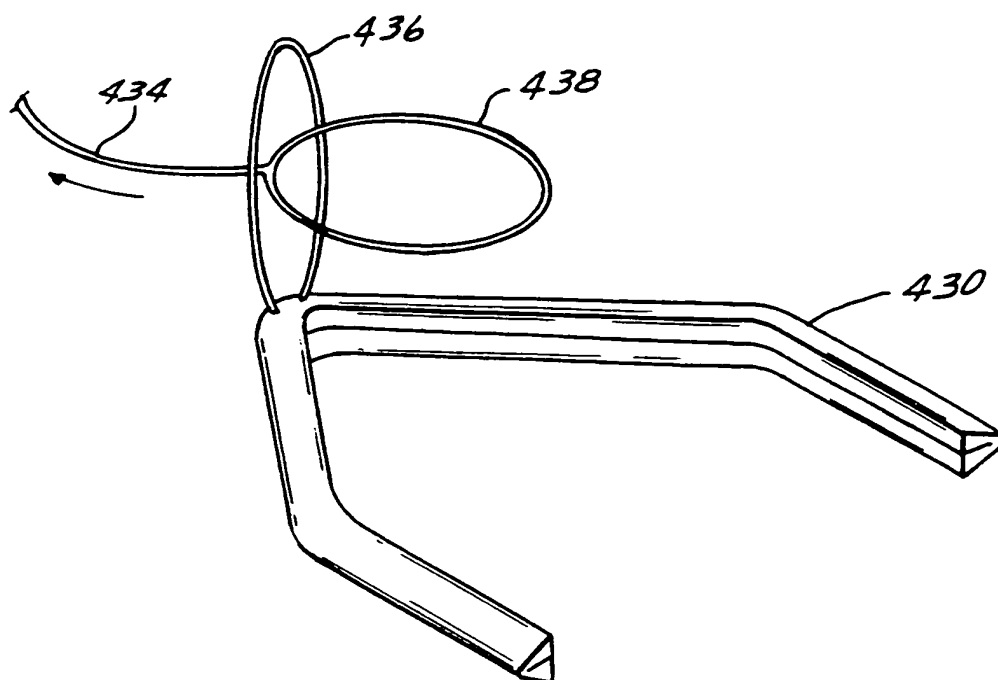


FIG. 22

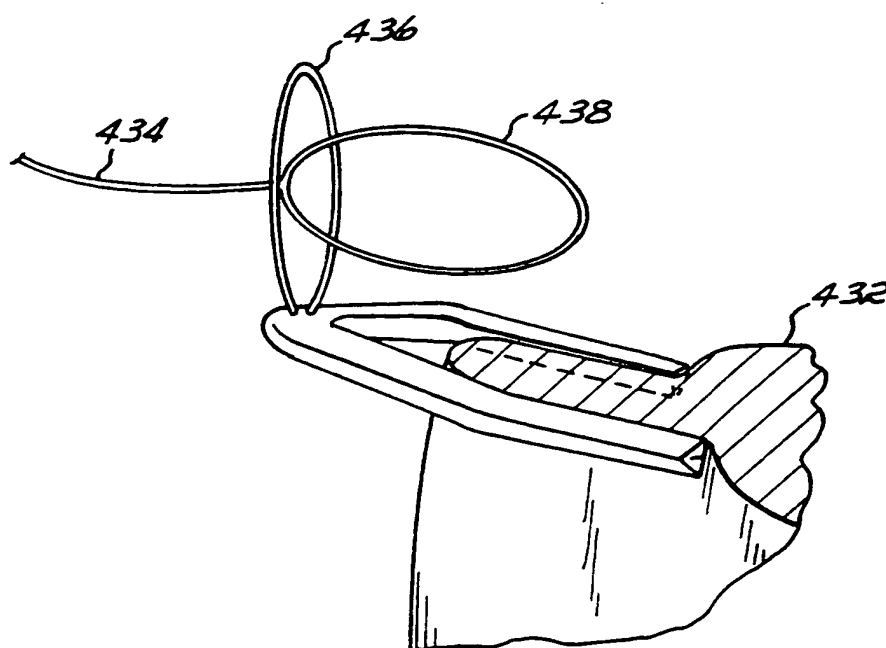


FIG. 23

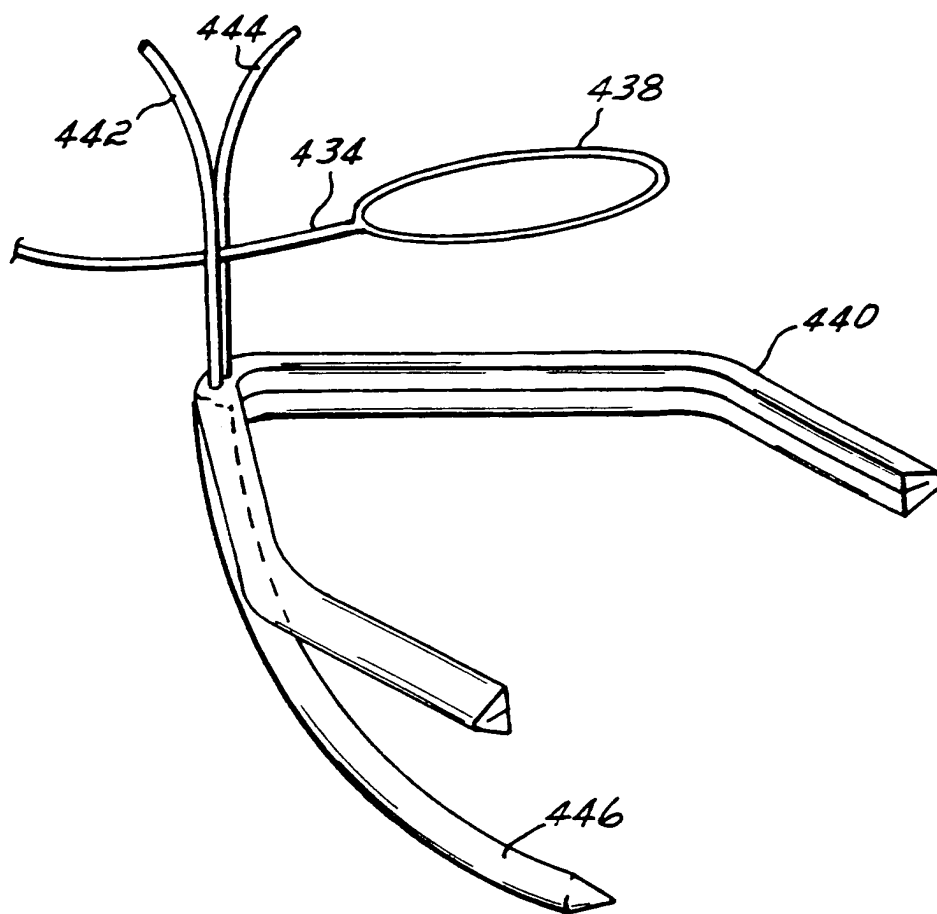


FIG. 24

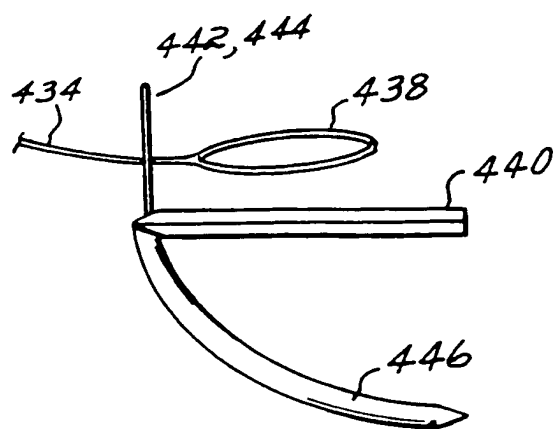


FIG. 25

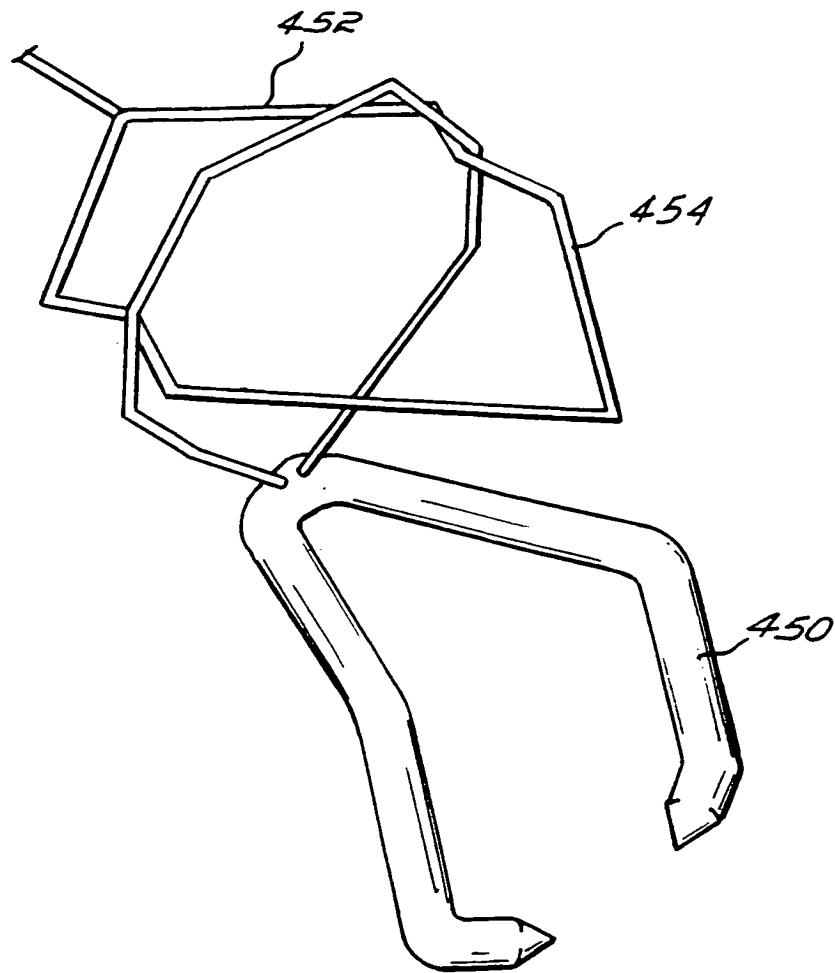


FIG. 26